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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,340	11/09/2000	Jeremy Francis Taylor	529642000800	5056

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EXAMINER
SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
1637	9

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/710,340	TAYLOR ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the c ver sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-20 and 22* is/are rejected.

7)☒ Claim(s) *13,21 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This action is in response to Paper No. 8, filed on April 24, 2003. Currently, claims 1-23 are pending. This action is made FINAL.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-11, 14-18, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallo et al. (Genetica (1997) 110: 1-12).

Assignment of an individual to a group or population of origin through the genotyping of said individual is a well-known technique that has been used for several years in the art. One of the many applications of genotyping and subsequent assignment of an individual to a particular group or population of origin is in the field of forensic science (pgs. 1-2). Given the broadest

reasonable interpretation of the claimed invention, forensic detection of criminal suspects reads on the claims as broadly written.

Specifically, when a crime occurs, law enforcement personnel obtain possible suspects. That is, they identify a set of candidate populations of origin, wherein each candidate population is characterized by genotype frequencies and allele frequencies at one or more marker loci (humans inherently have genotype frequencies and allele frequencies at one or more marker loci) (step (a)). Simultaneous to step (a) (i.e., identifying human beings), law enforcement personnel are also only selecting individuals who they believe may have committed the crime by using knowledge of the individual, such as, the whereabouts of the individuals at the time of the crime, or a description of the individual, such as, height, hair color, skin color, etc. (step (b)). Following step (b), law enforcement personnel will genotype the suspect (step c), as well as, DNA type the profiles of samples collected at the crime scene (see abstract). Once the two samples are analyzed, law enforcement will determine whether a match between the suspect's DNA profile and that found at the crime scene (see abstract) (steps d-g).

In other words, law enforcement determines a prior genotype probability by using knowledge about a subject (steps a-b), then genotypes the subject (step c), matches the genotype to samples taken at the crimes scene, giving a genotype probability (step d), and combining steps (b) and (d) to form a population posterior genotype probability (step e). Finally, law enforcement personnel would identify a most likely individual to the population, based on the largest population posterior genotype (step f) (i.e., an individual who may fit the description of someone who was around the crime scene at the time of the crime, as well as, someone's DNA

that matched some of the DNA found at the crime scene), and assign the individual to a most likely population of origin (step g).

In addition to the suggestions above, Gallo teaches that you can determine the frequency of the suspect's profile against the relevant population databases (see entire article). For example, Gallo suggests that a suspect's DNA sample "can be compared to databases from populations that predominantly live in the area where the crime was committed" (pg. 9).

Gallo does not teach the method steps as specifically outlined in the claimed invention, however, given the teachings of Gallo, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out the claimed methods in order to have achieved the benefit of a higher predictability of positively identifying the perpetrator of a crime.

5. Claims 1-11, 14-18, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Triggs (Science and Justice (2000) 40(1): 33-38).

Assignment of an individual to a group or population of origin through the genotyping of said individual is a well-known technique that has been used for several years in the art. One of the many applications of genotyping and subsequent assignment of an individual to a particular group or population of origin is in the field of forensic science (pg. 34). Given the broadest reasonable interpretation of the claimed invention, forensic detection of criminal suspects reads on the claims as broadly written.

Specifically, when a crime occurs, law enforcement personnel obtain possible suspects. That is, they identify a set of candidate populations of origin, wherein each candidate population is characterized by genotype frequencies and allele frequencies at one or more marker loci (humans inherently have genotype frequencies and allele frequencies at one or more marker loci)

(step (a)). Simultaneous to step (a) (i.e., identifying human beings), law enforcement personnel are also only selecting individuals who they believe may have committed the crime by using knowledge of the individual, such as, the whereabouts of the individuals at the time of the crime, or a description of the individual, such as, height, hair color, skin color, etc. (step (b)). Following step (b), law enforcement personnel will genotype the suspect (step c), as well as, DNA type the profiles of samples collected at the crime scene (pg. 34). Once the two samples are analyzed, law enforcement will determine whether a match between the suspect's DNA profile and that found at the crime scene (pg. 34) (steps d-g).

In other words, law enforcement determines a prior genotype probability by using knowledge about a subject (steps a-b), then genotypes the subject (step c), matches the genotype to samples taken at the crimes scene, giving a genotype probability (step d), and combining steps (b) and (d) to form a population posterior genotype probability (step e). Finally, law enforcement personnel would identify a most likely individual to the population, based on the largest population posterior genotype (step f) (i.e., an individual who may fit the description of someone who was around the crime scene at the time of the crime, as well as, someone's DNA that matched some of the DNA found at the crime scene), and assign the individual to a most likely population of origin (step g).

In addition to the suggestions above, Triggs teaches methods for assigning individuals from a population in mixed race populations, and more specifically outlines several different case scenarios for assignment based on the steps outlined above (see entire article).

Triggs does not teach the method steps as specifically outlined in the claimed invention, however, given the teachings of Triggs, it would have been obvious to one of ordinary skill in

the art at the time the invention was made to have carried out the claimed methods in order to have achieved the benefit of a higher predictability of positively identifying the perpetrator of a crime.

Response to Applicants Arguments

(With Respect to the 103 Rejections over Gallo and Triggs)

Applicants Arguments

1) The references do not teach the limitation of "determining a population prior genotype probability for an individual...", and specifically, Applicants argue, "there appears to be no actual calculation of any prior genotype probability for an individual".

2) The references do not teach the combination of steps (b) and step (d) to obtain a population posterior genotype probability for the individual and said candidate population.

3) The references nor the Examiner mention the missing claimed steps, and that the Examiner's motivation is only "a general desire to achieve the benefit of higher predictability".

Response to Applicants Arguments

Applicants arguments have been considered, but are not persuasive for the following reasons:

1) First, it is noted that the claims are not drawn to any "actual calculation" of a prior genotype probability. That is, the claims are drawn to "***determining*** a population prior genotype probability", and not "calculating" a population prior genotype probability, as is suggested by Applicants arguments.

Next, the specification (page 18, lines 13-15) states, "Prior probabilities are assigned based on knowledge that is available before the DNA sample from an individual was analyzed

for marker genotype information." Thus, the specification states that prior probabilities are merely "assigned", and not "calculated" as suggested by Applicant. Additionally, the specification broadly defines what is encompassed by "prior genotype probabilities", and only requires that the probabilities be "based on knowledge that is available before the DNA sample from an individual was analyzed for marker genotype information". That is, any information available before the DNA sample is collected can be considered as "knowledge" (as compared to a more specific prior genotype probability, such as giving a number score to those animals that are horned). Both Gallo and Triggs refer to comparing DNA profiles collected at the scene of a crime to "suspects" that have been apprehended. That is, before the actual genotyping occurs, a person is "determined" to be a suspect using knowledge available before the DNA sample from any individual is analyzed. The assignment of this person to the population of "suspect" meets the claim limitations.

2) The combination of step (b) and (d) is an end result of the teachings of Gallo and Triggs. That is, once an individual has been "determined" to be a suspect, the suspect is genotyped, and then the profile of the sample collected at the scene of the crime is determined and is compared with the profile suspect, as well as a database of other potential suspects. After the comparison is complete, the law enforcement personnel can identify a most likely population of origin (e.g., the individual who perpetrated the crime or an individual who did not perpetrate the crime), and assign the individual to the most likely population of origin.

3) The references do not explicitly outline the steps as claimed (e.g., the references do not use recitations such as "prior genotype probability" "population genotype probability", etc.). Despite not using Applicant's own lexicography (and interpreting said lexicography broadly), it

would be obvious to the skill artisan that Gallo and Triggs teach the claimed methods. Furthermore, the Examiner respectfully disagrees with Applicants assertion that it is not desirable to attain a higher predictability of assigning an individual to the most likely population of origin (e.g., the individual who perpetrated the crime or an individual who did not perpetrate the crime). In fact, the claim language requires all that is desired is the assignment of an individual "to the most likely population", which would necessarily mean that the higher predictability of assigning an individual, the better chance the assignment will be "to the most likely population". Therefore, Gallo and Triggs do provide the requisite motivation.

6. Claims 1-12, 14-20, 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Ron et al. (J of Diary Science (1996) 79(4): 676-681).

Ron teaches the misidentification rate in Israeli diary cattle population and its implications for genetic improvement. Specifically, Ron teaches that the misidentification (e.g., mistaken paternity or maternity) can be costly to the cattle industry (pgs. 676 and 679-680).

Ron teaches the DNA analysis of one hundred seventy-three cows, the progeny of 4 sires, which were sampled from 14 herds (steps a-b) (pg. 677). The cows were genotyped (step c) (pg. 677-78), and then compared to the assumed sire to determine a population genotype probability (step d) (pg. 678). The probabilities from step (b) and (d) were combined to determine the most likely population of origin of the cows (steps e-g) (pgs. 678-679). Ron teaches that by carrying out this assignment method, milk producers can save money (pg. 679-680).

Ron does not teach the method steps as specifically outlined in the claimed invention, however, given the teachings of Ron, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out the claimed methods in order to have

achieved the benefit of identifying mistaken paternity, in order to have achieved the benefit of reducing costs to milk producers.

Response to Applicants Arguments

Applicants Arguments

1) Ron does not teach the limitations of a "population prior genotype probability", population genotype probability" or "posterior population genotype probability". Ron does not teach the method steps encompassing these limitations.

2) Ron nor the Examiner mention the missing claimed steps, and that the Examiner's motivation is only "a general desire to achieve the benefit of higher predictability".

Response to Applicants Arguments

Applicants arguments have been considered, but are not persuasive for the following reasons:

1) Ron does teach "determining a population prior genotype probability for an individual…", since he teaches the selection of animals for determining the misidentification rate of dairy cattle, before the actual genotyping of the animals. The specification (page 18, lines 13-15) states, "Prior probabilities are assigned based on knowledge that is available before the DNA sample from an individual was analyzed for marker genotype information." That is, any information available before the DNA sample is collected can be considered as "knowledge" (as compared to a more specific prior genotype probability, such as giving a number score to those animals that are horned). In this case, even the mere assignment of a herd of cows for an experimental study satisfies the broadly defined characterization of a "population prior genotype probability". These cows were genotyped (step c) (pg. 677-78), and then compared to the

assumed sire to determine a population genotype probability (step d) (pg. 678). The probabilities from step (b) and (d) were combined to determine the most likely population of origin of the cows, which would then aid in determining whether the cows were misidentified (steps e-g) (pgs. 678-679).

Applicants assert Ron does not teach the limitations of the claims because Ron does not use Applicants' own lexicography. Applicants have not pointed out the alleged differences between the teachings of Ron and what is actually encompassed by Applicants own terms (e.g., "population prior genotype probability", "population genotype probability" or "posterior population genotype probability"). That is, Applicants have not provided any evidence to demonstrate that what Ron teaches could not be considered "population prior genotype probability", "population genotype probability" or "posterior population genotype probability", especially in light of the myriad of possible interpretations of these terms. There is no explicit definition as to what these terms mean, and therefore, these terms are interpreted broadly.

2) Ron does not explicitly outline the steps as claimed (e.g., Ron does not use recitations such as "prior genotype probability" "population genotype probability", etc.). Despite not using Applicant's own lexicography (and interpreting said lexicography broadly), it would be obvious to the skill artisan that Ron teaches the claimed methods. Furthermore, the Examiner respectfully disagrees with Applicants assertion that it is not desirable to attain a higher predictability of assigning an individual to the most likely population of origin (e.g., in order to help milk producers save money by correctly identifying cows). In fact, the claim language requires all that is desired is the assignment of an individual "to the most likely population", which would necessarily mean that the higher predictability of assigning an

individual, the better chance the assignment will be "to the most likely population". Therefore, Ron does provide the requisite motivation.

Conclusion

7. Claims 13, 21 and 23 are objected to for depending from a rejected claim.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-

3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
August 21, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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